

WHAT IS CLAIMED IS:

1. An isolated, substantially pure, or recombinant protein preparation of a human telomerase reverse transcriptase (hTERT) protein, or a variant thereof, or a fragment thereof.

2. An isolated, synthetic, substantially pure, or recombinant polynucleotide that is at least ten nucleotides to 3kb in length and comprises a contiguous sequence of at least ten nucleotides that is identical or exactly complementary to a contiguous sequence encoding a recombinant protein of claim 1.

3. The polynucleotide of claim 2 that encodes an hTERT protein or fragment.

4. A method of identifying a compound that modulates hTERT activity, said method comprising the steps of contacting an hTERT protein of claim 1 with said compound and measuring a change in a property or activity of said hTERT, wherein a statistically significant change in said property or activity identifies said compound as a modulator of hTERT activity.

5. The method of claim 4 wherein the compound is an inhibitor of hTERT activity.

6. A method of preparing recombinant telomerase, said method comprising contacting a recombinant hTERT protein of claim 1 with a telomerase RNA component under conditions such that said recombinant protein and said telomerase RNA component associate to form a telomerase enzyme capable of catalyzing the addition of nucleotides to a telomerase substrate.

7. The method of claim 6, wherein the hTERT protein has a sequence of

Figure 17.

8. The method of claim 7, wherein the hTERT protein is produced in an *in vitro* expression system.

5 9. The method of claim 6, wherein a said hTERT protein is substantially purified before said contacting.

10 10. A method for increasing the proliferative capacity of a vertebrate cell by introducing a recombinant hTERT polynucleotide of claim 3 into the cell, and wherein said sequence is operably linked to a promoter.

11. A method of detecting the presence of at least one telomerase positive human cell in a biological sample comprising human cells, said method comprising the steps:

- 15 a) measuring the amount of an hTERT gene product in said sample,
b) comparing the amount measured with a control correlating to a sample lacking telomerase positive cells,

20 wherein the presence of a higher level of the hTERT gene product in said sample as compared to said control is correlated with the presence of telomerase positive cells in the biological sample.

12. The method of claim 11, wherein said telomerase positive cells are cancer cells.

25 13. The method of claim 11, wherein the amount of an hTERT gene product is measured using an antibody.

30 14. The method of claim 11, wherein the amount of an hTERT gene product is measured using a nucleotide probe.

15. The method of claim 11, wherein said detecting involves diagnosing a telomerase-related condition in a patient, and said method further comprises the steps of:

- a) obtaining a cell or tissue sample from the patient;
- b) measuring the amount of an hTERT gene product in the cell or tissue; and,
- c) comparing the amount of hTERT gene product in the cell or tissue with the amount in a healthy cell or tissue of the same type;

wherein a different amount of hTERT gene product in the sample from the patient and the healthy cell or tissue is diagnostic of a telomerase-related condition.

16. The method of claim 15 wherein the amount is higher in said sample than in said healthy cell or tissue and said telomerase-related condition is cancer.

17. A method for treatment of a condition associated with an elevated level of telomerase activity within a cell, comprising introducing into said cell a therapeutically effective amount of an inhibitor of said telomerase activity, wherein said inhibitor is an hTERT polypeptide, an antibody that binds hTERT, or an hTERT polynucleotide.

18. The method of claim 17, wherein the inhibitor is an oligonucleotide comprising the sequence of Figure 17 or a subsequence or variant thereof.

19. The method of claim 18, wherein the oligonucleotide comprises nonstandard or derivatized bases or linkages between bases.

20. The method of claim 17, wherein the inhibitor is a polynucleotide that inhibits binding of endogenous hTERT to hTR.

add a2
add C1
add G2